SEP - 8 2003

K032524

510(k) Summary of Safety and Effectiveness

The following information provides data supporting a substantially equivalent determination between the ADVIA 60 with software version 1.6 and the predicate device, ADVIA 60 with software version 1.4.

The ADVIA 60 with software version 1.6 is based on the same fundamental technology as the predicate device cleared to market under K982802.

The Abbott Cell-Dyn 4000 (K961439) is also used as a predicate device to establish clinical accuracy of the ADVIA 60 with software version 1.6.

Intended Use
For *in-vitro* diagnostic use in the quantitative determination of blood cells and hematologic parameters in whole blood.

Device Description
The ADVIA 60 with software version 1.6 is a bench top, clinical laboratory instrument that analyzes *in-vitro* samples of whole blood specimens. The device reports a complete blood count (CBC) and 3-part WBC differential (LMG). The device operates as either a closed tube/closed system or open tube/open system. The ADVIA 60 can evaluate 5, 8, 16, or 18 hematology parameters depending on its internal configuration.

Principles of Operation
The ADVIA 60 with software version 1.6 is based on the same fundamental technology as the ADVIA 60 with software version 1.4.

The RBC/WBC/Plt parameters are counted based on impedance variation generated by the passage of cells through a calibrated micro-aperture.

The hemoglobin parameters are based on a modification of the manual cyanmethemoglobin method developed by the International Committee for Standardization in Hematology.

The WBC differential parameters are derived through a volumetric study of leukocytes after the use of a diluent and lysing reagent.

Similarities and Differences between the ADVIA 60 with software version 1.6 and ADVIA 60 with software version 1.4 (predicate device K982802)

The following table provides similarities and differences between ADVIA 60 with software version 1.6 and ADVIA 60 with software version 1.4.

Similarities/Differences	Characteristic	ADVIA 60 with Software Version 1.4	ADVIA 60 with Software Version 1.6
Similarities	Intended Use	Hematology analyzer for *in-vitro* diagnostic use	Same as predicate device.
	Accuracy	As specified in product labeling.	Equivalent to predicate device.
	Precision	As specified in product labeling.	Equivalent to predicate device.
Difference	Linearity	As specified in product labeling.	Expanded linearity claims

Similarities and Differences between the ADVIA 60 with software version 1.6 and Abbott Cell-Dyn 4000 (predicate device K961439)

The following table provides similarities and differences in the principles of measurement between ADVIA 60 with software version 1.6 and Abbott Cell-Dyn 4000.

Similarities/Differences	Characteristic	Cell-Dyn 4000	ADVIA 60 with Software Version 1.6
Similarities	RBC/Plt count	Aperture impedance	Aperture impedance
	Hgb measurement	Spectrophotometer	Spectrophotometer
Differences	WBC Count	Light scattering	Aperture impedance
	MCV	Light scattering	Calculated from Hct
	WBC Differential	Multiple angle polarized light scatter separation	Aperture impedance

Conclusion

The test results included in this submission demonstrate that the ADVIA 60 with software version 1.6 has equivalent accuracy and precision to the ADVIA 60 with software version 1.4. Expanded linearity claims with version 1.6 are supported with the results included in this submission.

Date August 1, 2003

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer Corporation
511 Benedict Avenue
Tarrytown, New York 10591-5097

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 8 2003

Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Bayer HealthCare LLC
Diagnostics Division
511 Benedict Avenue
Tarrytown, NY 10591-5097

Re: k032524
Trade/Device Name: ADVIA 60 Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: August 1, 2003
Received: August 15, 2003

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K032524

Device Name: ADVIA 60 hematology analyzer

Indications for Use:
For *in-vitro* diagnostic use in the quantitative determination of blood cells and hematologic parameters in whole blood.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-CounterUse _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032524